

## REMARKS

### SPECIFICATION

Paragraphs 2, 82, 84, 85, 86, 90, 91, 116 and 126 have been amended to correct for informalities. No new matter has been introduced.

### CLAIMS

Claims 1, 3-6, 8-15, 18-21, 23-24, 26-27 and 29-35 are currently pending in the application. Claims 13-14 and 32-33 have been withdrawn from consideration. In the Final Office Action of August 18, 2006, the Examiner rejects claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34 and 35 on obviousness grounds. Additionally, the Examiner objects to claim 1 for an informality involving redundant text.

Claims 1, 15, 21 and 31 have been amended to correct for informalities. In addition, Applicants amend claims 1, 18 and 29 to further clarify the claimed invention and cancel claims 2 and 22. The amendments to claims 1, 15, 18, 21, 29 and 31 will not require a new search or consideration.<sup>1</sup>

The rejections to claims 1, 3-6, 8-15, 18-21, 23-24, 26-27 and 29-35 are traversed. Applicants respond to the obviousness rejection as subsequently recited herein, and respectfully request reconsideration and further examination of the present application.

#### A. Applicants overcome the Examiner's objection by amending claim 1.

The Examiner objects to claim 1 for having redundant text. According to the Examiner, "[t]he amended claim [1] recites in lines 5-7 that the device comprises 'a metal structural element' 'comprised of metallic material', which is redundant and unnecessary." (See first paragraph, page 2 of the Final Office Action dated August 18, 2006.)

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<sup>1</sup> Amendments to claim 1 include removing an informality and incorporating limitations of previously written claim 2, which has now been cancelled. Similarly, claim 18 is amended to incorporate limitations of previously written claim 22, which has now been cancelled. In addition, amendments are made to claims 18 and 29 to add the term "only by" and "only", in reference to the point of attachment between the structural element and the metal thin film. This "only" limitation has already been considered by the Examiner in previously written claim 1, subsection (c). Accordingly, Applicants' amendments do not require a new search or consideration.

In view of the Examiner's remarks, Applicants amend line 6 of claim 1 to delete the expression "comprised of a metallic material." Applicants submit that the above-described amendment of claim 1 obviates the Examiner's objection and thus respectfully request that the objection be withdrawn.

B. Applicants traverse the Examiner's rejection under 35 U.S.C. §103(a) of pending claims 1, 3-6, 8-15, 18-21, 23-24, 26-27 and 29-35 as being unpatentable over EP 0 759 730 B1 to Burmeister et al. in view of U.S. 6,585,764 to Wright et al.

Applicants have carefully reviewed the remarks made by the Examiner in the Final Office Action of August 18, 2006 and have thoroughly reviewed both the previously cited reference, EP 0 759 730 B1 to Burmeister et al. (hereinafter referred to as "*Burmeister*"), and the newly cited reference U.S. 6,585,764 to Wright et al. (hereinafter referred to as "*Wright*"). For this 35 U.S.C. §103(a) rejection to be proper, the Examiner must establish a *prima facie* case of obviousness by showing that there is some teaching, suggestion, or motivation in the prior art to make the specific combination or modification suggested by the Examiner. *See In re Raynes*, 7 F.3d 1037, 1039 (Fed. Cir. 1993). Obviousness cannot be established by hindsight combination or modification to produce the claimed invention. *See In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991). Moreover, for the Examiner to establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *See* MPEP 2143.03; *see also In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974).

I. The Examiner's obviousness rejection of claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34 and 35 is improper because not all the recited claim limitations are taught or suggested by the cited prior art.

In his Final Office Action of August 21, 2006, the Examiner fails to establish *prima facie* obviousness because neither the *Burmeister* reference nor the *Wright* reference, even when combined together to form a hypothetical construct, teaches or suggests every limitation recited in independent claims 1, 18 and 29. More specifically,

neither the *Burmeister* reference nor the *Wright* reference teaches a “microporous metal thin film,” as is recited in independent claims 1, 18 and 29, or an “affixation member” or “at least one projection,” as recited in claims 1 and 29, respectively.

a. “Microporous metal thin film”

Departing from his earlier position, as described in the Non-Final Office Action of March 31, 2006, the Examiner now acknowledges that the *Burmeister* reference in fact does not teach a microporous metal thin film. *See* page 3 lines 2-3 of the Final Office Action. Applicants construe this acknowledgement by the Examiner acknowledges as admission that his previous anticipation rejection, made in the Non-Final Office Action of March 31, 2006 and based solely on the *Burmeister* reference, was improper.

Changing course, the Examiner now argues that while the *Burmeister* reference does not teach a metal thin film that is microporous, the *Wright* reference does teach a metal film that is microporous. The Examiner further argues that it would have been obvious to one of ordinary skill in the art to have combined the teachings in the *Wright* reference with those in the *Burmeister* reference, to form a drug-delivery stent that would purportedly render obvious Applicants’ claimed invention.

Applicants respectfully disagree. Applicants submit that the *Burmeister* reference fails to even disclose a thin film, let alone one that is microporous. To further clarify, Applicants submit that the only embodiment described in the *Burmeister* reference which could possibly include an element that can be even be interpreted as a film is the embodiment depicted in *Burmeister* Fig. 3, which illustrates a cross-section of a bi-layered stent with an outer martensitic layer 34. None of the other embodiments in the *Burmeister* reference depict or describe a stent, wherein one element of the stent overlies another element. Applicants submit that the martensitic layer 34 shown in *Burmeister* Fig. 3 does not qualify as a thin film as defined by those skilled in the art because its too thick, as compared to the thin film described in the pending application. Furthermore, Applicants note that this *Burmeister* embodiment lacks affixation elements. Instead, there is merely an interface between the martensitic layer 34 and the austenitic layer 32 of the stent. Contrary to the Examiner’s inference, an interface between two

layers of a bi-layered stent does not constitute an affixation element. Furthermore, contrary to the Examiner's suggestion,<sup>2</sup> Applicants submit that none of the other embodiments depicted or described in the *Burmeister* reference illustrate affixation elements. The *Burmeister* Figs. 1-16 pointed out by the Examiner do not show affixation elements.) If the Examiner disagrees with the Applicants' reading of the *Burmeister* reference, Applicants kindly request that the Examiner point out more specifically where in the *Burmeister* specification or figures, he sees "multiple affixation elements" that affix structural elements to a thin film.

Applicants further note that contrary to the Examiner's assertions, the *Wright* reference does not teach a "microporous metal thin film," as recited in independent claims 1, 18 and 29. Applicants submit that what the Examiner construes in the *Wright* reference as a "film" is not a considered a "film" by those skilled in the stent arts. Rather, what the Examiner construes as a "film" in fact constitutes structural elements that form part of *Wright's* stent. *Wright's* structural elements actually correspond to Applicants' stent's structural support elements, not Applicants' microporous metal thin film. Thus, Applicants submit that the Examiner has failed to establish that the *Wright* reference even teaches a thin film.

What's more, the Examiner has failed to establish that the structural elements in the *Wright* reference (inaccurately construed by the Examiner to be a thin film) possess microporous qualities. The term "micro" is commonly understood to mean "very small." See *Merriam Webster's Online Dictionary* at <<http://www.m-w.com/dictionary/micro>>. The term "porous" is commonly defined to mean "permeable to fluids." See *Merriam Webster's Online Dictionary* <<http://www.m-w.com/dictionary/porous>>. Thus, under the common interpretation as understood by a layperson and as understood by a person of ordinary skill in the stent arts, the expression "microporous metal thin film" clearly

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<sup>2</sup> On page 2 of the Final Office Action of August 18, 2006, the Examiner claims that:

*Burmeister* discloses the same invention being an implantable endoluminal graft comprising a nitinol film cover (34) having uniform pattern of elongated slots (figure 11a and 11b) and an underlying nitinol structural support element (32) that have multiple affixation elements throughout the device along the support elements cylindrical sinuous elements and the affixation projections shown in figures 1-16.

means a metal thin film with very small openings therein which render the film permeable to fluids. In other words, for a thin film to be considered microporous, it must have openings passing through the film thickness. In the pending application, Applicants describe (in great detail) a microporous metal thin film with openings passing through the thickness of the thin film in the following passages:

Paragraph 103, Page 21, Lines 6-7:

The openings 19 permit cellular and sub-cellular physiological matter, such as proteins, to pass through the openings 19.

Paragraph 104, Page 22, Lines 20-22:

Alternative embodiments of the present invention can have a varying size of each of the plurality of openings in the microporous metal thin film covering so that cellular migration occurs through each opening, without permitting fluid flow there through.

Paragraph 104, Page 22, Lines 26-30

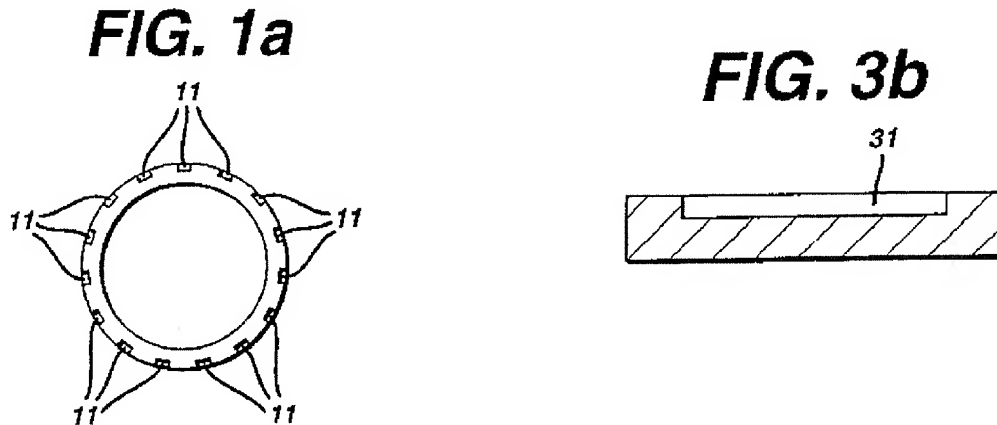
For example, endoluminal saphenous vein grafts may be fabricated with openings in the microporous metal thin film covering that serve the dual function of permitting transmural endothelialization while also excluding biological debris, such as thrombus from passing through the wall thickness of the graft, effectively excluding detrimental matter from entering the circulation.

Paragraph 124, Page 28, Lines 27-29

A plurality of generally circular openings 256 pass through the metal thin film material 258 in an area bounded by a pair of circumferentially extending elongate slots 252 and a pair of circumferentially extending elongate slots 254.

In stark contrast to Applicants' disclosure, the *Wright* reference fails to disclose a thin film, let alone one that is microporous, wherein microporous openings transverse the thickness of the film. As clearly illustrated in *Wright* FIG. 1a and FIG. 3b reproduced below, the *Wright* reference does not teach the "microporous" feature possessed by Applicants' claimed metal thin film. Instead, it merely teaches a stent with structural

elements possessing reservoirs or channels 11 or 31 which do not transverse the thickness of the structural elements.



Because neither the *Burmeister* reference nor the *Wright* reference, even when combined together to form a hypothetical construct, teach or suggest a microporous metal thin film as recited in independent claims 1, 18 and 29, and cannot therefore, by themselves, provide the proper basis for rendering obvious claims 1, 18 and 29, the Examiner's rejection is improper. *See* MPEP 2143.03; *see also In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974) (concluding that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art). Accordingly, Applicants submit that independent claims 1, 18 and 29 are allowable over the art cited and of record.

Likewise, dependent claims 3-6, 8-12, 15, 19-21, 23-24, 26, 27, 30-31, 34 and 35 are also allowable over the art cited and of record. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious under 35 U.S.C. §103(a), the claims dependent therefrom are also nonobvious). Accordingly, Applicants submit that dependent claims 3-6, 8-12, 15, 19-21, 23-24, 26, 27, 30-31, 34 and 35 are also in condition for allowance and kindly requests that the Examiner withdraws the obvious rejection.

b. "Affixation member" or "at least one projection"

With specific regard to claims 1, 3-6, 8-12, 15, 29-31, 34 and 35, Applicants submit that both the *Burmeister* reference and the *Wright* reference are devoid of any teaching, expressed or implied, of “an affixation member” as recited in claim 1, or of “at least one projection” as recited in claim 29. Contrary to the Examiner’s contention, Applicants submit that the contact points described in the *Burmeister* reference do not constitute an affixation member or a projection, as understood by those skilled in the art. An affixation member or projection limitation confers a tangible structural element. In contrast, a contact point as described in the *Burmeister* reference confers no such structural element.

For the foregoing reasons, unless the Examiner can show a specific reference in the *Burmeister* reference or the *Wright* reference to an affixation member or a projection, the Examiner’s obviousness rejection of claims 1, 3-6, 8-12, 15, 29-31, 34 and 35 is improper.

2. The Examiner’s obviousness rejection of claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34 and 35 is improper because the Examiner’s suggested motivation for combining the *Burmeister* reference with the *Wright* reference is flimsy.

Applicants also note that the stents in the *Burmeister* reference are different from the stents in the *Wright* reference, with each having different functions and structural configurations. Thus, without engaging in impermissible hindsight there is no clear motivation for one of ordinary skill in the art at the time of the invention to modify the stent described in the *Burmeister* reference to incorporate reservoirs or channels as taught by *Wright*. See *Ruiz*, 234 F.3d 654, 665 (Fed. Cir. 2000) (explaining that the temptation to engage in impermissible hindsight is especially strong with seemingly simple mechanical inventions); see also *Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) (“[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight”); see also *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (“Particular findings must be made as to the reason the

skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed”).

Without further detailed explanation from the Examiner with regard to a motivation for coming the two references, Applicants submit that the Examiner’s combination of the *Burmeister* reference with the *Wright* reference is improper.

3. Amendments to claims 1, 18 and 29 further distinguish the claimed invention from the prior art cited and of record.

Applicants amend claim 1 to recite “at least one affixation member positioned near either a proximal end or a distal end of the microporous metal thin film covering and at a corresponding end of the metal structural support element ...” The amendment incorporates the limitations of previously written claim 2 into amended claim 1. Thus, no new matter has been entered. A similar amendment is made to claim 18 by incorporating previously written claim 22. Additional amendments are made to claims 18 and 29 to incorporate the “only” limitation, in reference to the point of attachment between the metal thin film and the structural element. As described previously in Section A, these amendments to claims 18 and 29 to incorporate the “only” limitation do not require a new search or consideration because this limitation was already in previously written claim 1.

While Applicants believe previously written claims were already patentably distinguished from the cited prior art,<sup>3</sup> Applicants further defines the claimed invention by amending claims 1, 18 and 29 to incorporate the above-described “only” limitations and limitations relating to the affixation member being positioned near the terminal ends of the metal thin film and a corresponding end of the structural element. These amendments further distinguish the claimed invention from the cited prior art. Applicants submit that none of the cited prior art references teach a stent with a structural element affixed to a microporous metal thin film via *an affixation member positioned near the terminal ends of the metal thin film and at a corresponding end of the structural*

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<sup>3</sup> Applicants’ amendment to claims 1, 18 and 29 does not amount to abandonment of any subject matter in the application, and the Applicants reserve the right to pursue some or all of such subject matter in this application, or in one or more divisional or continuation applications.



*element.* Thus, the Examiner's withdrawal of the obviousness rejection is kindly requested.

Summary

To conclude, because the *Burmeister* reference fails to teach a microporous metal thin film, let alone a microporous metal thin film covering a structural support element, the Examiner's obviousness rejection of pending claims 1, 3-6, 8-12, 15, 18-21, 23-24, 26, 27, 29-31, 34 and 35 is improper. In addition, claims 1, 3-6, 8-12, 15, 18-21, 23-24, 26, 27, 29-31, 34 and 35 are further distinguished from the cited prior art by featuring an affixation member/projection that is not disclosed in the *Burmeister* reference or the *Wright* reference. For the foregoing reasons, Applicants kindly request that the Examiner withdraws the obviousness rejection of claims 1, 3-6, 8-12, 15, 18-21, 23-24, 26, 27, 29-31, 34 and 35.

Applicants submit that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited. Should the Examiner believe that there are any outstanding matters capable of resolution by a telephone interview, the Examiner is encouraged to telephone the undersigned attorney of record.

Any amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

This Paper is being concurrently filed with an Amendment Transmittal, which includes a fee calculation sheet and any applicable requests for Extension of Time. Other than those stated in the Amendment Transmittal, no additional fees are believed

necessitated by the filing of this Paper. Should any such additional fees be required, the Director is hereby authorized to deduct them from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Respectfully submitted

A handwritten signature in black ink, appearing to read "J-12" with a stylized flourish at the end.

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